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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,081	07/16/2003	Arne Sippens Groenewegen	020061-000410US	1847
20350	7590	03/22/2006	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP			BERTRAM, ERIC D	
TWO EMBARCADERO CENTER			ART UNIT	
EIGHTH FLOOR			PAPER NUMBER	
SAN FRANCISCO, CA 94111-3834			3766	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/622,081	Applicant(s) GROENEWEGEN ET AL.	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 25-37 in the reply filed on 3/14/2006 is acknowledged.
2. Applicant's cancellation of claims 1-24 in the reply filed on 3/14/2006 is also acknowledged.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, after reviewing the specification, it is unclear to the examiner how the magnitude of an ischemia may be determined merely by determining the location of an occlusion. There are sections regarding the magnitude of an infarction, but that differs greatly from an ischemia.
5. In the response to this action, please particularly point out the sections of the specification which enable this subject matter.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Medema et al. (US 6,217,525, hereinafter Medema). Medema discloses a method for detecting cardiac ischemia through comparison of patient data. Medema describes obtaining multiple-lead ECG data from a group of patients experiencing ischemia and then confirming ischemia and sorting the acquired data into groups based on the correlation of ischemic data (Col. 17, line 36-Col. 18, line 34). The confirmation is completed by using cardiac markers such as ST elevation, T-wave amplitude and QRS area measures (Col. 18, lines 21-25). Finally, a location of the ischemia may be determined by comparing the correlated group data to the patient data (Col. 22, lines 13-22).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medema ('525) in view of Levine et al. (US 6,058,328, hereinafter Levine).

Medema, as described above, discloses the applicant's basic invention with the exception of measuring the data while a patient is undergoing coronary angioplasty.

Attention is directed to the secondary reference of Levine, that discloses recording ECG data from patients during a percutaneous transluminal coronary angioplasty (PTCA) induced ischemia (Col. 33, lines 1-10). Therefore, it would have been obvious to one of

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ordinary skill in the art to record ECG data during PTCA induced ischemia in order to collect patient data under safer conditions since it is a controlled ischemia.

12. Regarding claim 26, Medema discloses that the data can be grouped by ischemic location, including anterior, inferior and other (Col. 18, lines 8-12). It is the Examiner's position that an anteroseptal location and a posterolateral location would inherently be used as groups if that is where the ischemia took place.

13. Claims 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medema ('525) in view of Levine ('328) and further in view of Mlynash et al. (US 6,615,075, hereinafter Mlynash). Medema, as modified above, discloses the applicant's basic invention with the exception of generating a map based on the ECG data and ischemic region data. Attention is directed to the reference of Mlynash, that discloses creating integral or potential maps based on ECG data, specifically a QRST segment, and sensor position data (Col. 12, lines 20-59). As shown in figure 12, Mlynash uses the sensor position to show ECG characteristics relating to that position. Mlynash also discloses that these are merely examples of maps that could be created, stating that these techniques could be used for any isolated cardiac activity (Col. 12, lines 51-55). Therefore, it would be obvious to one of ordinary skill in the art at the time of the applicant's invention, that, once the ischemia locations had been determined by the method of Medema, one could further use the mapping method of Mlynash in order to visually correlate the positions to ECG data.

14. Regarding claim 30, it is old and well known in the art that when comparing data between known subjects and unknown subjects, the more the data differs from the

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known, the larger the problem is. Therefore, it would have been obvious to one of ordinary skill in the art that the magnitude of the difference between known ischemia data and unknown patient data directly correlates to the magnitude of the problem.

15. Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medema ('525) in view of Mlynash ('075). Medema, as described above, discloses the applicant's basic invention with the exception of generating a map based on the ECG data and ischemic region data. Attention is directed to the reference of Mlynash, that discloses creating integral or potential maps based on ECG data, specifically a QRST segment, and sensor position data (Col. 12, lines 20-59). As shown in figure 12, Mlynash uses the sensor position to show ECG characteristics relating to that position. Mlynash also discloses that these are merely examples of maps that could be created, stating that these techniques could be used for any isolated cardiac activity (Col. 12, lines 51-55). Therefore, it would be obvious to one of ordinary skill in the art at the time of the applicant's invention, that, once the ischemia locations had been determined by the method of Medema, one could further use the mapping method of Mlynash in order to visually correlate the positions to ECG data.

16. Regarding claim 37, Medema discloses that the data can be grouped by ischemic location, including anterior, inferior and other (Col. 18, lines 8-12).

Conclusion


17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ransbury et al. (US 6,584,343) discloses a method for determining myocardial infarctions using integral and potential maps.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 9-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

Eric D. Bertram
Examiner
Art Unit 3766

EDB